[DISCUSSION DRAFT]

118TH CONGRESS 2D SESSION

H.R.

To amend title XI of the Social Security Act to exclude from antikickback and other sanctions certain travel and lodging arrangements between manufacturers of drugs and individuals being administered such drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

A BILL

- To amend title XI of the Social Security Act to exclude from antikickback and other sanctions certain travel and lodging arrangements between manufacturers of drugs and individuals being administered such drugs, and for other purposes.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. SHORT TITLE.
 - 4 This Act may be cited as the " Act
 - 5 of 2024".

| 1 | SEC. 2. EXCLUDING FROM ANTIKICKBACK AND OTHER |
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| 2 | SANCTIONS CERTAIN TRAVEL AND LODGING |
| 3 | ARRANGEMENTS BETWEEN MANUFACTUR- |
| 4 | ERS OF DRUGS AND INDIVIDUALS BEING AD- |
| 5 | MINISTERED SUCH DRUGS. |
| 6 | Section 1128B of the Social Security Act (42 U.S.C. |
| 7 | 1320a-7b) is amended— |
| 8 | (1) in subsection $(b)(3)$ — |
| 9 | (A) in subparagraph (J), by striking at the |
| 10 | end "and"; |
| 11 | (B) in subparagraph (K), by striking at |
| 12 | the end the period and inserting "; and"; and |
| 13 | (C) by adding at the end the following new |
| 14 | subparagraph: |
| 15 | "(L) an arrangement described in subsection (i) |
| 16 | between a manufacturer of a drug and an individual |
| 17 | who is prescribed such drug."; and |
| 18 | (2) by adding at the end the following new sub- |
| 19 | section: |
| 20 | "(i) For purposes of subsection (b)(3)(L), an ar- |
| 21 | rangement described in this subsection between a manu- |
| 22 | facturer of a drug and an individual who is prescribed |
| 23 | such drug is an arrangement entered into on or after Jan- |
| 24 | uary 1. 2025, that satisfies each of the following: |
| 25 | "(1) The arrangement provides for payment or |
| 26 | reimbursement by the manufacturer for transpor- |

1 tation, lodging, meals, or other incidental expenses 2 specified by the Secretary connected with such ad-3 ministration and relating to travel to and from the 4 facility at which such drug is to be administered, for 5 the individual and up to two caregivers of the indi-6 vidual (as determined appropriate by the manufac-7 turer, taking into account the individual's age and 8 medical needs) during any portion of the period dur-9 ing which such individual is being administered such 10 drug (including initial visits to such facility before 11 such administration, and followup visits to such fa-12 cility after such administration, relating to the ad-13 ministration of such drug). 14 "(2) The arrangement does not provide for pay-15 ment or reimbursement by the manufacturer for 16 transportation, lodging, meals, or other incidental 17 expenses described in paragraph (1) if the manufac-18 turer knows that the individual is eligible to receive 19 at no cost, such transportation, lodging, meals, or 20 other out-of-pocket expenses, as applicable, from the 21 facility at which the drug is administered to the in-22 dividual. 23 "(3) The manufacturer does not advertise the 24 arrangement and makes good-faith efforts to ensure 25 that the availability of such arrangement is not dis-

| 1 | closed to such individual until after such drug is pre- |
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| 2 | scribed to such individual, provided that such manu- |
| 3 | facturer does not interfere with a health care pro- |
| 4 | vider's ability to furnish such individual with any in- |
| 5 | formation determined appropriate by the provider. |
| 6 | "(4) If the arrangement provides for payment |
| 7 | or reimbursement by the manufacturer for transpor- |
| 8 | tation described in paragraph (1), such payment or |
| 9 | reimbursement is only for— |
| 10 | "(A) travel that is practical and conven- |
| 11 | ient, taking into account the individual's mobil- |
| 12 | ity or medical needs, which may include ground |
| 13 | transportation, air transportation, or transpor- |
| 14 | tation by train; |
| 15 | "(B) the costs directly associated with the |
| 16 | travel for the individual and caregivers as de- |
| 17 | scribed in paragraph (1), such as airfare, taxes, |
| 18 | tolls, gas, or other fees; and |
| 19 | "(C) travel between the individual's resi- |
| 20 | dence and the closest facility that is available to |
| 21 | administer such drug (or between any lodging |
| 22 | where such individual is staying in relation to |
| 23 | such administration and such facility). |

| 1 | "(5) If the arrangement provides for payment |
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| 2 | or reimbursement by the manufacturer for lodging |
| 3 | described in paragraph (1), such lodging is— |
| 4 | "(A) reasonable based on the individual's |
| 5 | age and medical needs; |
| 6 | "(B) near the facility at which such indi- |
| 7 | vidual is to be administered such drug; and |
| 8 | "(C) only provided during the period de- |
| 9 | scribed in paragraph (1). |
| 10 | "(6) If the arrangement provides for payment |
| 11 | or reimbursement by the manufacturer for meals |
| 12 | other incidental expenses described in paragraph (1), |
| 13 | the amount of such payment or reimbursement does |
| 14 | not exceed the per diem rate in effect for meals and |
| 15 | incidental expenses in the geographic area in which |
| 16 | such facility is located (as established by the General |
| 17 | Services Administration) for the individual and for |
| 18 | each caregiver allowed under the arrangement pur- |
| 19 | suant to paragraph (1). |
| 20 | "(7) The individual— |
| 21 | "(A) is determined to have income that |
| 22 | does not exceed the median income applicable to |
| 23 | a family of the size involved in the geographic |
| 24 | region (as specified by the Secretary) in which |
| 25 | such individual resides: and |

| 1 | "(B) lives more than 1 hour of driving dis- |
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| 2 | tance (or 50 miles) from the nearest facility |
| 3 | that administers such drug and is accepting pa- |
| 4 | tients. |
| 5 | "(8) Such an arrangement is offered by the |
| 6 | manufacturer to individuals regardless of the facility |
| 7 | involved in the administration of the drug and re- |
| 8 | gardless of the insurance status of the individual. |
| 9 | "(9) The arrangement requires the individual to |
| 10 | agree to not request reimbursement from any Fed- |
| 11 | eral health care program for any costs for which |
| 12 | payment or reimbursement is made by the manufac- |
| 13 | turer under the arrangement. |
| 14 | "(10) The manufacturer certifies that the man- |
| 15 | ufacturer does not bill or shift the costs of the ar- |
| 16 | rangement to any of the Federal health care pro- |
| 17 | grams.". |